Ethiopian Food and Drug Authority

Guideline on Medical Products Special import permit

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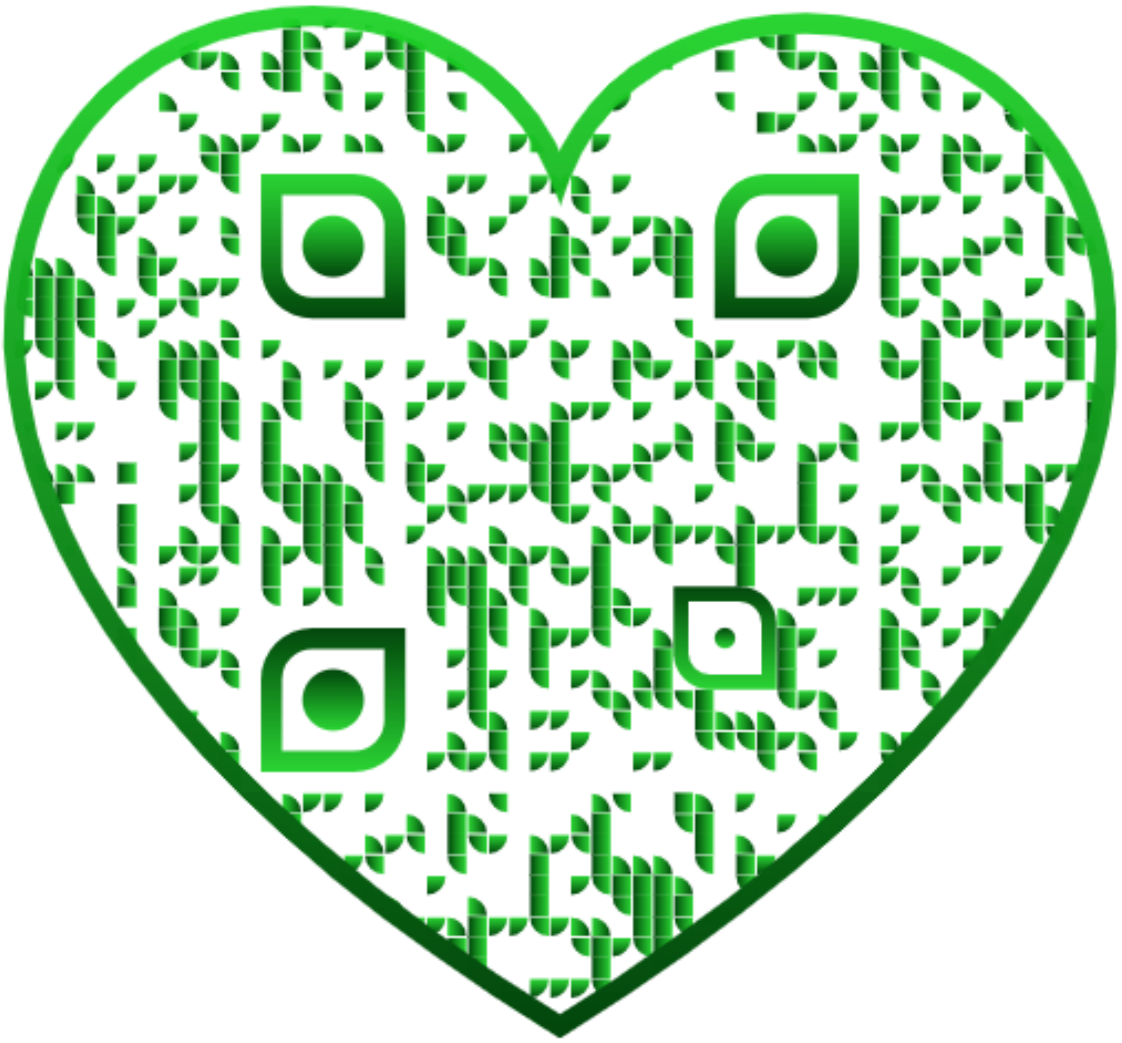
Addis Ababa, Ethiopia



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Abbreviations

eRIS	Electronic Regulatory Information System
CE	Conformite Europeenne
GMP	Good Manufacturing Practice
MA	Marketing Authorization
MOH	Ministry of Health
NGO	Non-Governmental Organization
NRA	National Regulatory Authority
QMS	Quality Management System
SDG	Sustainable Development Goal
UNICF	UN International Children Fund
WHO	World Health Organization

1. Background

Medical products cannot be treated in the same way as ordinary commodities. Their manufacture and subsequent handling within the distribution chain must conform to prescribed standards and be rigorously controlled. These precautions serve to assure that patients receive quality assured medical products, and to prevent the infiltration of substandard and suspected falsified medical products into the supply system.

The availability of medical products might be limited owing to economic constraints, difficulty in meeting norms and standards, lack of resources, urgent demand for emergency use or blockade by conflicts. These conditions may lead to market penetration by substandard and suspected falsified medicines, which pose hazards for public health and exacerbate the situation. In light of this, devising strategies to speed up approval and custom clearance are deemed crucial to ensure quality-assured medical products for patients

Access to safe, effective, quality and affordable essential medicines and vaccines is identified as central to the achievement of universal health coverage, in target 3.8 of the Sustainable Development Goals (SDGs). Furthermore, the United Nations declared that access to essential medicines is a key element of universal human rights. However, access to medicines and vaccines continues to be a challenge worldwide, mainly for low- and middle-income countries.

National medicines regulatory authorities are trying their best to improve access of medical products for public use. To accomplish this, most NRAs develop and implement different laws, strategies, systems and others. In Ethiopia, the Ethiopian food and drug authority (EFDA) has exerted lots of efforts to improve the availability of these products; such as developing and implementing strategy meant to boost marketing authorization, creating system to provide a pre-import permit for products that do not have private market interests, medicine used for unmet medical need and emergency conditions.

The Authority is empowered by law to grant a permit for the importation or use of unregistered medicine or medical device in compelling circumstances as indicated in article 20(15) of the Food and Medicine Administration Proclamation (Proclamation No. 1112/2019). Article 5(10) of the regulation that defines the organization, powers and duties of the Authority (Regulation No. 531/2023) also gives the authority and power to establish a system that enables utilization of regulated product for emergency response. Medicine Marketing Authorization Directive (

Directive No. 963/2023) which is developed in consistent with these laws, also listed the grounds under which the authority may grant special import permit for the unregistered medicines imported for natural or man-made disaster or similar emergency aid; use of diplomatic mission; and medicines for unmet medical needs that lack the attention of private importers. The authority has discretionary powers to waive product authorization requirements in respect of consignments of medical products imported in response to emergency situations, specific intended use as in clinical trials, donation and in response to requests from clinicians for limited supplies of an unlicensed product needed for the treatment of a specific named patient.

Therefore, this guideline is developed to guide applicants by providing detail requirements and conditions that are needed to grant special import permit for the unregistered medical products during emergency; medical products for unmet medical need, for research, for exhibition and when there is shortage of products in the country.

2. Definition

Authority means Food and Drug Authority of Ethiopia

Special import permit is a system in which medical products are allowed to be imported from outside the country by institutions or individuals under special circumstance such as during emergency, unmet medical need, shortage of medical products in the local market, donation, for personal use, for health promotion and for clinical investigation or researches.

Pre-Import permit is a permit letter issued by the Authority to institution for importing product medical products under special circumstance such as during emergency, unmet medical need, shortage of medical products, for clinical investigation, for research, for exhibition or samples for health promotion.

Institution is a governmental or non-governmental organization that submits a request for import of medicines and medical equipment to the authority to carry out the procurement of medicines and medical equipment.

An individual is a medical client who has received a prescription from a medical professional to help him use a medicine or medical device.

Port clearance – is official permission to bring medical products into the country (Ethiopia) for sales or distribution for use.

Medical product – is a term that includes medicines, vaccines, diagnostics and medical devices or emergency health kits containing medicine and medical products intended for human use, for medical research and health promotion presented in its finished dosage or package form that is subject to control by legislation under the mandate of the authority. It also contains raw materials and bulk products for purpose of medicine or medical devices manufacturing by local pharmaceutical manufacturers or research as well as components, spare parts, accessories of medical device.

Emergency health kit- is a standardized health kit containing medicines and medical supplies to meet different health needs in humanitarian emergencies and disasters

3. Objective

The objective of this guideline is:

- To provide guidance for medical product manufacturers, suppliers, donors, importers, health institutions, and recipients on the regulatory requirements for special import permit.
- To assist EFDA experts on requirements that needs to be fulfilled while requesting special import permit (pre-import permit) of medical products.
- To control importation of medical products those do not fulfill regulatory requirements as well as prevent importation of poor quality, ineffective and unsafe medicine and minimize the accumulation of non-functional, and non- effective medical device.

4. Scope

This guideline is applicable for pre-import permit and importation of medical products for public health emergency use, for unmet need, for shortage of medical products in the local market, for clinical trials, for health promotion, raw materials for medical products manufacturers and health institutions (healthcare investment).

5. Medical Products Importation through Special Permit

The medical product may be imported under special circumstance through the following persons:

i. Charity institutions (including International NGO's operating in Ethiopia, and ;overseas health institutions, health professionals associations, individual donors etc)
ii. Government procurement agency or private Importers
iii. Government and Non- Governmental Health institutions (Hospitals, health centers, clinics etc)
iv. Health Research Institutions (including clinical trial investigators) and educational institutions
v. Recipients of donations (MoH, Health bureau's, local NGOs, etc)
vi. Religious institutions
vii. Individuals: importing of medical products for medical purposes
viii. Service for campaign health works
ix. Other governmental and non-governmental organizations
x. Local Pharmaceutical manufacturers

6. Requirements for Special Import Permit of Medical Products

6.1. General Requirements

1) Any institution or individual who submits an application for the import of medical products under special conditions from a foreign country can be approved by the authority when it is confirmed that the medical product is not available in the country.
2) When the medical product is for individual purpose, evidence such as prescription paper should be provided
3) If these medical products are for private organization employee use, a proof of evidence that show the products are not available in Ethiopian market should be provided.
4) Medicines to be imported under special circumstance (through pre-import permit) into the country should be in the master medicine list or the registered medicine list
5) A medical product that is not registered or not included in the country's master medicine/medical device list may be granted a pre-import permit if it meets the following necessary requirement:-

i. Medical Products that are in the list of priority items identified by the federal Ministry of Health to be used for the health emergency or health system restoration

ii. It has a conditional approval (got emergency use authorization) by EFDA or other reliable regulatory agencies or

iii. If the product is include in emergency use list by international organizations(eg WHO).

iv. If the reasons stated by the applicant for a special permit and importing unregistered medical products is satisfactory such as clinical trial, research or investment related and health promotion

~~v.~~ The medical products to be imported have no registered therapeutic equivalent (alternative) products available in country or

6) There should be evidence for existing shortage or projected expected shortage of the medical product in healthcare system of the country.

7) If the applicant is a charitable organization, a letter of confirmation stating the type and amount of medical products requested by the institution receiving the assistance should be submitted and it should be confirmed that the requested medical products meet the standards set by the authority's medicines and medical equipment donation control directives.

8) For medical devices, if the donated medical device has been used, it should be reconditioned, tested and all essential parts, accessories and working materials included before shipment. Evidence document for the indication of such statements should be included in the application for pre-import approval of such devices. However, the medical device shall not be donated if the equipment has been in used for more than five years.

9) Importation of medicines and medical devices for clinical trial investigation should be done only after approval of the clinical trial authorization application by the Authority. Such evidence (copy of authorization letter) should be provided during submission of the application for pre-import permit approval of medicines and medical devices.

10) Individual who want to import medical products for personal use or custom made medical device should have prescription paper from authorized health professional. The

prescription paper should indicate the type, description, and the quantity of the medical products. In this case, there is no need of pre-import permit application and applicant can clear the product at port of entry by showing the prescription paper.

11) Under special circumstances, the applicant requesting a pre-import permit to import medical products for the use of the institution's employees should have evidence of support from the relevant government body and should provide relevant information about the employees working at the institution. The applicant`s request should specify that the medical products are imported for their employee use only. Once these products are imported, the applicant should ensure that the organization has a medical record for utilization of the imported products and a report that indicates use of the imported medicine and medical device for the company's employees and reports should be submitted to EFDA branch or regional regulatory body when requested.
12) A letter of support is required from the relevant government body or health institution to grant permission for the special pre-import permit of medicines and medical devices for the purpose of campaign health services. The fate of the leftover medicines and used and/or unused medical devices after the campaign is over should be clearly stated.
13) For medical devices, the devices to be imported under special circumstance (pre-import permit) should meet the general safety and quality standards requirements. The devices should :-
    a) Be fully operational at the system and sub-system levels, and that all essential accessories and supplies are available.
    b) Meet existing safety and performance specifications provided by the manufacturer, and/or meet ESI standards or ISO standards.
    c) Registered in the country of origin or provide justification for absence of such health problem in the country of origin.

6.2. Specific Requirements

6.2.1. Requirements for importation of medical products for emergency use by public &private health institutions, UN agencies, NGOs and other relevant firms

a) The medical products to be imported for emergency use must be listed in the supplies identified for curbing or mitigating the health risks associated with the emergency situation.

b) The importation of medical products by health institutions shall be considered only where there is an unmet medical need as a result of emergency induced shortages.

c) The applicant should be registered and licensed, as appropriate, by the federal or regional executive organ

d) For health institutions, the applicants should submit support letter from MOH or Regional health bureau that the health institution has the capacity and designated to give the health care services related to the emergency.

e) If the request is for importing unregistered medical products, the applicant should provide clinical justification that the unregistered medical product is required to meet special clinical needs arising in the course of health care practice, which includes preventing out-of-stock situation for established medical product or novel medical products for the health emergency.

f) The applicant needs to submit the following documents for review

i. Online filled application in eRIS. To facilitate the application Annex 1 indicated
ii. Proforma invoice- The Proforma invoice should indicate the following for each medical product to be imported:
    a) Profoma invoice number and date
    b) Name of the supplier.
    c) Name of the manufacturer.
    d) Country of origin/manufacture.

e) Trade or proprietary name and (vi) The International Non Proprietary name (generic name) of the product. In the case of the product containing more than one active ingredient, the name and strength of each shall be stated.
f) Strength, for medicine
g) The quantity to be imported for each drug, its unit value, total value and acceptance currency.
h) Currency
i) Mode of shipment (sea, air, road)
j) Destination port of entry
k) Signature and stamp of the supplier

iii. Instructions for use, product insert, or user manual by the product owner
iv. MA certificate from country of origin or other NRAs for medicines
v. For Medical devices, MA from country of origin or other NRAs or CE certificate or device specific performance test report or clinical justification that the unregistered medical device is safe and performed as intended
vi. A copy of valid GMP (QMS, ISO 13485 for medical device) compliance certificate of the medical product manufacturers.
vii. A copy of the importing/recipient health institution`s license or COC of the recipient, if the institution is private health institution
viii. Valid NGO/charity License for concerned governmental organization of the institution is NGOs
ix. Declaration on end use & distribution plan by donor or recipient
x. Supporting letter MOH or RHB for NGOs, for UN agencies and other relevant firms
xi. Donation certificate, if the product is for donation.

g) Used medical devices can be imported if it is cleaned, disinfected, sterilized (as appropriate), reconditioned and tested. It should be accompanied by all relevant supporting documents for reconditioning.

h) Refurbished medical devices can be imported after be ingested and reconditioned, and if all essential parts, accessories and working materials are included before shipment. Adequate supporting evidence and documents for approving restoring of the device to its original working condition should be provided.

6.2.2. Requirements for importation of medical products for unmet medical need and shortage

a) The importation of medical products by applicant or health institutions shall be considered only where there is an unmet medical need and evidence that there is a shortage of medical products in the local market.

b) The applicant should be registered and licensed, as appropriate, by the federal or regional executive organ

c) For health institutions, the applicants should submit support letter from MoH or Regional health bureau that the health institution has the capacity and designated to give the health care services.

d) If the request is for importing unregistered medical products, the applicant should provide clinical justification that the unregistered medical product is required to meet special clinical needs arising in the course of health care practice.

e) The applicant needs to submit the following documents for review

   i. Online filled application in eRIS. To facilitate the application Annex 1 indicated
   ii. Proforma invoice as indicated above.
   iii. Instructions for use, product insert, or user manual by the product owner
   iv. MA certificate from country of origin or other NRAs for medicines
   v. MA from country of origin or other NRAs or CE certificate or device specific performance test report or clinical justification that the unregistered medical device is safe and performed as intended
   vi. A copy of valid GMP (QMS, ISO 13485 for medical device) compliance certificate of the medical product manufacturers.

vii. A copy of the importing/recipient health institution`s license or COC of the recipient, if the institution is private health institution

viii. Valid NGO/charity License for concerned governmental organization of the institution is NGOs, if applicable

ix. Supporting letter MoH or RHB for NGOs, for UN agencies and other relevant firms

x. Donation certificate, if the product is for donation, if applicable.

f) Used medical devices can be imported if it is cleaned, disinfected, sterilized (as appropriate), reconditioned and tested. It should be accompanied by all relevant supporting documents for reconditioning.

g) Refurbished medical devices can be imported after be ingested and reconditioned, and if all essential parts, accessories and working materials are included before shipment. Adequate supporting evidence and documents for approving restoring of the device to its original working condition should be provided.

6.2.3. Requirements for importation of medical products for unmet medical need and shortage

a) The importation of medical products by applicant or health institutions shall be considered only where there is an unmet medical need and evidence that there is a shortage of medical products in the local market.

b) The applicant should be registered and licensed, as appropriate, by the federal or regional executive organ

c) For health institutions, the applicants should submit support letter from MoH or Regional health bureau that the health institution has the capacity and designated to give the health care services.

d) If the request is for importing unregistered medical products, the applicant should provide clinical justification that the unregistered medical product is required to meet special clinical needs arising in the course of health care practice. Unregistered products

imported for unmet need and due to shortage shall shift to the normal marketing authorization route within a maximum of two years.

e) The applicant needs to submit the following documents for review:

   i. Online filled application in eRIS (see Annex 1 for filling the application)
   ii. Proforma invoice as indicated above.
   iii. Instructions for use, product insert, or user manual by the product owner
   iv. MA certificate from country of origin or other NRAs for medicines
   v. MA from country of origin or other NRAs or CE certificate or device specific performance test report or clinical justification that the unregistered medical device is safe and performed as intended
   vi. A copy of valid GMP (QMS, ISO 13485 for medical device) compliance certificate of the medical product manufacturers.
   vii. A copy of the importing/recipient health institution`s license or COC of the recipient, if the institution is private health institution
   viii. Valid NGO/charity License for concerned governmental organization of the institution is NGOs, if applicable
   ix. Supporting letter MoH or RHB for NGOs, for UN agencies and other relevant firms
   x. Donation certificate, if the product is for donation, if applicable.

f) Used medical devices can be imported if it is cleaned, disinfected, sterilized (as appropriate), reconditioned and tested. It should be accompanied by all relevant supporting documents (maintenance & cleaning directive) for reconditioning.

g) Refurbished medical devices can be imported after be ingested and reconditioned, and if all essential parts, accessories and working materials are included before shipment. Adequate supporting evidence and documents for approving restoring of the device to its original working condition should be provided.

6.2.4. Requirements for importation of Raw and bulk product by local manufacturer

a) The pharmaceutical manufacturer shall have a valid manufacturing license in Ethiopia.

b) The proposed raw material under consideration should be pharmaceutical grade.

c) The applicant needs to submit the following documents for review:

i. Online filled application
ii. Proforma Invoice
iii. A copy of valid GMP (QMS, ISO 13485 for medical device) compliance certificate of the Active raw materials and bulk products manufacturers

6.2.5. Requirements for importation of medical product for Clinical investigation or other researches

a) Sample of actual labeling materials and/or color print (Outer packaging & immediate container) of investigation product should show the following information:

i. The product is clinical trial material e.g. “For use in clinical trial only” or “For use in research purpose only”

ii. Product name or unique code (if blinded)

b) The applicant needs to submit the following documents for review

i. Online filled application
ii. Proforma Invoice
iii. Certificate(s) of Analysis (CoA) of investigational product (s) and comparator product (if applicable)
iv. Copy of the letter of approval of clinical trial by the Authority or support letter and approved research proposal from the researchers organization
v. Copy of valid GMP certificate of Manufacturer issued by the competent NRA in the country of manufacture.
vi. For medicines, CPP issued by competent NRA in the country of manufacture (if applicable)
vii. Device/Proof of maintenance of cold chain (if applicable)

6.2.6. Requirements for importation of medical product for healthcare investment purpose

Pre-import permit is permitted for capital equipment (medical devices) only. The applicant needs to submit the following documents for review:

i. Online filled application
ii. Proforma Invoice
iii. MA from country of origin or other NRAs or CE certificate or device specific performance test report or clinical justification that the unregistered medical device is safe and performed as intended
iv. A copy of valid GMP (QMS, ISO 13485 for medical device) compliance certificate of the medical product manufacturers.
v. Instructions for use, product insert, or user manual by the product owner
vi. Supporting letter indicating the medical device is for new investment and or expansion of the health facilities
vii. License of the institution
viii. Used medical devices can be imported if it is cleaned, disinfected, sterilized (as appropriate), reconditioned and tested. It should be accompanied by all relevant supporting documents for reconditioning.
ix. Refurbished medical devices can be imported after be ingested and reconditioned, and if all essential parts, accessories and working materials are included before shipment. Adequate supporting evidence and documents for approving restoring of the device to its original working condition should be provided.

6.2.7. Requirements for importation of medical products by different firms for their employee use

a) The importation of medical products by firms other than health institutions shall be considered only when confirmed shortage exists.

b) The applicants should submit support letter from relevant government agency or MOH or Regional health bureau that guarantees the firm is a legal entity engaged in investment and has the capacity to use the medical products related to the emergency.

c) If the request is for importing unregistered product, the authority may approve or reject the request based on clinical justification of unregistered medical product.

d) The applicant needs to submit the following documents for review

i. Online filled application
ii. Proforma Invoice (as above)
iii. Instructions for use, product insert, or user manual by the product owner
iv. Support letter from relevant government agency or MOH or Regional health bureau
v. MA certificate from country of origin or other NRAs for medicine
vi. For medical device, MA from country of origin other NRAs, CE certificate, or device specific performance test report or clinical justification that the unregistered medical device Number of staff, names and full address of employee
vii. A copy of valid GMP (QMS, ISO 13485 for medical device) compliance certificate of the medical device manufacturers
viii. A copy of the importing institution`s license (which could be part of a firm engaged in other business)
ix. Declaration of conformity (for medical device)

e) Refurbished medical devices can be imported after being tested and reconditioned, and if all essential parts, accessories and working materials are included before shipment. Adequate supporting evidence and documents for approving restoring of the device to its original working condition should be provided.

6.2.8. Requirements for importation of medical products for health promotion

a) An applicant who applies for a pre-import permit application to import medicine and medical device and use it for health promotion must fulfill the following requirements:

i. Supporting letter and statement from the relevant government body
ii. Statement of intended benefit
iii. A letter of support from the exhibition organizer
iv. A letter of commitment stating that the exhibitor will return to the country of origin after completion of the exhibition, or proof of legal transfer to be used in the country.
v. Medicines and medical devices imported into the country with a sample label; indicating that it is "for sampling or demonstration or non-clinical purposes only".

7. Application Procedure

7.1. Any applicant requesting special import permit (pre-import permit) of medicine and medical device should apply through the authority's Electronic Regulatory Information System (eRIS). Once the application is submitted through eRIS, the authority will evaluate the application and accompanying justification documents for pre-import permit to import medicine and medical devices under special circumstances.

7.2. If the application meets the prescribed requirements, the applicant will be required to pay applicable service fee for reviewing and approving pre-import permit of applicant as per the current rate of fee service regulation. The Authority will issue an import permit as set out in the eRIS of the Authority.

7.3. An application will be rejected if it does not meet any of the importation requirements. An applicant will be informed a rejection decision through eRIS by stating reason(s) for rejection of such application.

7.4. Pre-import permit applications will be reviewed within three (3) working days and applications must be submitted before the arrival of the consignment.

7.5. The pre-import permit granted by the Authority should be valid for one year only. However, under a certain circumstance the Authority may extend for more time as needed.

7.6. Pre-import permits are not required for medical products imported for personal use including custom made devices.

8. Controls during importation

8.1 Visual examination of the products and other relevant information checks will be undertaken at the ports of entry. The inspectors check the size of the consignment against invoices, bills

or delivery slips, and attention will be given to the nature and conditions of the packaging and labeling.

8.2 The external package should be intact and should not show any signs of damages or infiltrations that may change the inner content

8.3 For medical products imported for personal use, the product information and the quantity of the items will be verified against the prescription paper.

8.4 When necessary, samples may be taken to EFDA or other accredited quality control laboratory for analysis prior to the release of the consignment. In such instances, the consignment should be retained in quarantine at approved sites.

8.5 The sampling and subsequent physical and chemical analysis of medical products, for emergency use will be considered as fast track based on established procedures of the laboratory.

8.6 A consignment suspected of being substandard or contain items that are not authorized should be placed in quarantine until appropriate regulatory measures are taken.

8.7 In order to confirm that the medicine or medical device imported into the country is used for its intended purpose, the authority may request the institution that has obtained a special pre-import permit to provide evidence or report when it deems it necessary.

8.8 Transportation, handling, storage and distribution of medicine or medical device entering the country under special conditions must meet the transportation, storage, handling and distribution requirements set by the relevant directives and guidelines of the authority according to the type and condition of the product.

8.9 The authority is also conducted quality, safety and efficacy monitoring and surveillance after the product being imported through this procedure for campaign treatment or vaccination.

Reference:

1. Food and Medicines Administration Proclamation, Proclamation No. 1112/2019, Federal Negarit Gazette of the Federal Democratic Republic of Ethiopia.
2. Definition of Organization, Powers and Duties of the Ethiopian Food and Drug Authority Council of Ministers Regulation, Regulation No. 531/2023
3. Medicine Marketing Authorization Directive (No. 963/2023), Ethiopian Food and Drug Authority.
4. Guideline on Requirements of Medical Devices Clearance at Port of Entry, 1st Edition, EFDA, January, 2022.
5. Guidelines for Importation and Exportation of Pharmaceutical Products and Raw Materials. Doc. No. TFDA/DMC/MMI & E/G/004, 2nd Edition, July 2011. Tanzania Food and Drug Authority.

Annex I: Pre-Import submission format

Pre-Import Permit application Form

(Medicine/Medical Device/Spare part/Accessories)

To:- ----------

Dear Sirs,

Please kindly supply the following goods subject to the General terms and conditions of contact shown overleaf and mentioned below.
MEDICINES BACK ORDERS

S/NO	Description of the Item	Unit	Qty	Unit price in ($, €, £, or ¥ e.t.c.)	Total price in ($, €,£, or ¥ e.t.c.)	Can try of origin

Port of Entry -------- ----------

Method (Item) of Payment ----------

Accompanying Documents

- **Packing list**
- **Chamber zed Invoice**
- **Air way Bill /Bill of Lading**
- **Certificate of Origin**
- **Batch Analysis Certificate**

TERMS AND CONDITIONS OF CONTRACT

Products should have minimum as per import, export and wholesaler control directive of the authorityof its shelf life on arrival at Addis Ababa/port of entry

Language used for writing label leaflet and other documents shall be in English

All packing should be suitable for road, air and sea transport under tropical conditions

The label of the immediate container should at least include:-

The name of the product

Pharmaceutical dosage form and route of administration

Qualitative and quantitative compassion of active ingredients(s)

Quantity in container Technical directions for use

- Handling and storage requirements
- Batch number manufacturing and expiry dates
- Name and address of Manufacturer

1. Accompanying invoice should be as per purchase order including Batch number manufacturing and expiry date of each item
2. Every product should be accompanied by a leaflet in its immediate container. A leaflet must bear adequate information for use and should at least include:
    - The name of the product brand and generic.INN
    - Description appearance ,Pharmaceutical dosage form and route of administration
    - Qualitative and quantitative composition of active ingredients
    - Clinical pharmacology, indication(s) Warnings, precautions, contra-indications, adverse reactions (side effects).
    - Dosage and administration/directions of use
    - Over dosage, storage instruction package quantity, Name and address of manufacture